FIELD OF THE INVENTION

The present invention relates to the field of dispensing medication to a living being. Although mainly intended for use by human patients requiring infusions of a drug, such as insulin, glucose, heparin, or any of various other chemotherapeutic agents, the invention extends to use in any living body (such as domestic animals) and to the infusion of any liquid (such as blood) or colloidal suspension, or gas or granulated solid, which may provide a curative or healing effect. Although a principal use envisioned is for implantable devices, it is also envisioned that it could be used external to a living being for the infusion of medication.

IMPLANTABLE, PROGRAMMABLE MEDICATION
INFUSION SYSTEM

TECHNOLOGICAL CONTEXT OF THE INVENTION

Various techniques and devices have been suggested and are currently under study which address the problem of dispensing a drug or other medicative liquid into a living body. Of these techniques and devices, however, redundant safety features and flexibility achieved by programming dosage inputs are rarely contemplated.

One liquid infusion device discussed in U. S. Patent No. 4077405 by Haerton et al discloses a controllable dosing arrangement which provides for human operator interaction. A syringe forces liquid through a pressure valve into a supply reservoir and a bellows pump forces drug from the reservoir through a flow limiter into the body. Haerton et al teaches an "overpressure" technique where liquid in the reservoir is at a pressure above that at the discharge point. This device fails to address various safety problems such as leakage, excessive pumping, and excessive requests for drug. In particular, should the input control valve in Haerton et al leak, a flood of liquid would enter the body because of the pressure differential and the lack of any back-up safety mechanism. No provision for detecting leaks in the device, for signalling malfunctions, for restricting the number of or quantity of drug doses, or for monitoring proper operation of the device is suggested.

Like Haerton et al, U. S. Patent No. 3692027 by Ellinwood teaches an implanted, self-powered drug dispenser having a bellows pump which is fed through and expels drug through valves, in particular one-way valves. The Ellinwood device is not programmable; it varies

dosage by opening and closing portals or selecting a dose or medication from one of a plurality of pumps having different dosage volumes and/or different medications stored therein. Safety redundancy such as pressure integrity checks during filling, leakage problems, patient and doctor interaction with the dispenser, and dosage input programming are not considered.

An invention of Blackshear (U.S. Patent No. 3731681) shows another infusion pump without redundant safety features. While disclosing an implanted bellows pump arrangement fed through a self-sealing plug, Blackshear does not look for pressure integrity before filling the device with drug. Further, because there is no input valve and because the pressure in the device is above that of the body in which it is implanted, leakage in Blackshear can be dangerous. Further, like Haerton et al and Ellinwood, Blackshear does not disclose an antechamber which can serve various safety purposes.

Richter (U. S. Patent No. 3894538) considers, in a medicine supplying device, one safety feature: an exit plug for preventing contaminants from entering the device and for limiting drug outflow. The flow from the Richter device does not provide a smooth pulsatile flow of drug which is infused over a relatively long period. It further fails to disclose any means for reliably controlling or varying the flow rate.

A device by Jacob (U. S. Patent No. 4033479), like other techniques, provides a bellows pump chamber which maintains drug at a "constant internal pressure." A

valve opens to release drug into a body and the bellows varies the chamber volume to maintain constant pressure. It is not of importance to Jacob how much pressure there is in the chamber -- it is above body pressure -- but, rather, the concern is to keep pressure constant. Leakage out from the valve and the spurting of drug into the body under relatively high constant pressure would appear to be problems inherent in the Jacob device.

Several recent publications have also underscored the need for an implantable medication infusion device. Two articles by Rohde et al ("One Year of Heparin Anti-coagulation;" <u>Minnesota Medicine</u>; October, 1977 and "Protracted Parenteral Drug Infusion in Ambulatory Subjects Using an Implantable Infusion Pump"; <u>American Society for Artificial Internal Organs Transactions</u>, <u>Volume XXIII</u>; 1977) describe an implantable infusion pump which comprises a hollow disk separated into two chambers by a bellows. A volatile fluorocarbon in the outer chamber forces drug from the inner chamber through a filter and catheter into a patient. Filling of the inner chamber is accomplished by penetrating a self-sealing septum which apparently forms a wall of the inner chamber. The condensation of the fluorocarbon provides energy for cyclical pumping. No antechamber, no check for pressure integrity before filling or during operation, no programming means, and no patient or doctor interaction with the device are contemplated.

Finally, an article by Spencer ("For Diabetics: an electronic pancreas;" <u>IEEE-Spectrum</u>; June, 1978)

discusses current trends in the implantable drug pump
field. Programming the rate of drug flow over time
depending on food intake is mentioned. Efforts in the
development of an implantable bellows pump are also
discussed. Spencer further mentions the use of alarm
sounds if a pump fails to provide drug in accordance
with the preprogrammed rate. The Spencer article
generally discusses drug dispenser technology but fails
to address many specific problems. As in other cited
work, redundant safety features such as an antechamber;
leak detection; distinctive subcutaneous stimulation to
indicate various device malfunctions; safe method of pro-
gramming the device regardless of work, food-intake, or
time schedules; and maintaining the reservoir pressure
below ambient body pressure so that a leak would result
in body fluids, ~~entering~~ being inadvertently released into the device as opposed to a fatal
dose of drug entering the body (at a high, constant
pressure) are not considered.

SUMMARY OF THE INVENTION

In a field where safety and reliability are paramount, the present invention provides extensive redundancy to prevent device failure.

The present medication infusion system provides an antechamber which is normally filled with saline solution to act as a buffer between the medication intake point and the major medication reservoir in the device. The reservoir may contain a fatal amount of drug or other medication. It is thus isolated from the body by a filter, one-way inlet valve, the saline-containing antechamber and a septum providing a self-sealing opening to the antechamber. Further, the reservoir is at a pressure below the ambient body pressure. Thus, even if the inlet valve and septum leak, body fluids would enter the antechamber and slowly ooze into the reservoir through the flow-impeding filter. Any other leak of medication from the reservoir would be sensed by a fluid detector outside the reservoir. Similar safety back-ups are provided at the outlet output of the reservoir which is provided with two one-way valves and a filter.

The outlet, however, also is provided with a deformable wall which combines with the outlet filter to yield an exponentially decaying flow of medication. This smooth flow over a long, predetermined period provides enhanced safety and flow control. Also at the outlet is an element for correlating medication requests with medication dispensing, thus providing an operational indicator and safety feature.

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Also, for safety, a filling procedure is provided which insures that medication is not injected into the device until pressure integrity at the input is determined.

In the mechanical pump itself, the amount of medication pulsing it can provide is restricted by a pressure limit intrinsic in the pump design.

In programming the present system, convenience and safety are again major concerns. A flexible, maximum running integral program for limiting medication dosage inputs communicated by a patient satisfies not only a patient's need for proper amounts of medication but also satisfies a variable work and eating schedule requirement of the patient. In addition to a programmable rate of medication input, a hardwired limit is also included. If requests exceed the limits set by the program, the hardwired limits will inhibit the pulsing of excessive medication into the patient.

Finally, the system provides a history of medication infusion which a physician can read out through telemetry means. This telemetry means is also used to program and check the system.

DESCRIPTION OF THE DRAWINGS

Figs. 1 and 2 show a front and top view, respectively, of the implantable portion of the present medication infusion system.

Fig. 4 shows, in detail, the mechanical construction of a pulsatile pump element of the invention.

Fig. 5 is a block diagram showing the electronics of the invention.

Fig. 6 shows a method of programming the rate of medication infusion into a patient by use of the maximum running integral dosage limiting technique.

Figs. 7 and 8 are illustrative of a patient programming unit. Fig. 7 shows a front view illustrating a sample apparatus for selecting dosage depending on recognized body condition factors. Fig. 8 shows a rear portion which provides information relative to the last programming of the patient programming unit.

DESCRIPTION OF THE INVENTION

Referring to Fig. 1, the various portions of the implantable programmable medication infusion system are shown. An implantable portion 2 in a patient's body can be programmed either by the medication programming system 1 or by the patient's programming unit 400. Commands from the medication programming system 1 emitted from the communication head 300 are transmitted to electronics in the implantable portion 2 in order to program and effectuate the infusion of medication into the body in a safe, controlled fashion. The medication programming system 1 is also capable of reading information out of the implantable portion 2 concerning the amount of medication dispensed over a specified time period and furthermore the medication programming system 1 is capable of calibrating the per pulse of medication of the implantable portion 2. A medication injection unit 7 is connected to a double hypodermic syringe 4 which is used to provide medication to an implantable medication reservoir 18 (shown in Figs. 2 and 3) included within the implantable portion 2. Fill commands to the medication injection unit 7 emanate from a medication programming unit 3. A patient's programming unit 400 is controlled by the user to request doses of medication. The dosage requests are controlled by safety units embodied in fixed hardware elements and programmable elements found in the implantable portion 2. To recharge a rechargeable cell contained within the implantable portion 2, an external charging head 9 connected to a battery charging unit 11 is included. The need for the charging head 9 and battery charging unit 11 can be obviated by the inclusion in the implantable portion 2 of a power supply (such as a lithium cell) which is of sufficient lifetime

to negate the need for recharging. The medication pro-

gramming unit 3 outputs to a paper printer 13 which provides

hard, readable output that can be readily interpreted by a physician

Referring now to Figs. 2 and 3, the implantable portion

2 of an implantable programmable medication infusion

system is shown. Medication is provided to the implant-

able portion 2 by means of a double hypodermic syringe 4

which penetrates the skin 5 and a self-sealing rubber

septum

diaphragm 6 which covers an antechamber 8 in leak-proof

fashion. Medication is introduced into the antechamber

8 through syringe 4 under pressure the level of which

is controllable externally. A reservoir chamber 10, in

which the medication is stored under relatively constant

pressure, is fed from the antechamber 8 via a ceramic

filter 12 and an inlet pressure valve 14 which permits

flow only from the antechamber 8 into the reservoir

chamber 10 when the pressure differential between them

exceeds a predetermined threshold.

The inlet ceramic filter 12 performs various functions.

Besides filtering contaminants from medication being fed

into the reservoir chamber 10, the ceramic filter 12

serves to limit the rate of medication flow from the

antechamber 8 into the reservoir chamber 10 or, conversely,

from the reservoir chamber 10 into antechamber 8 should

the inlet pressure valve 14 leak or malfunction.

Further, should the self-sealing rubber septum diaphragm 6 leak,

the ceramic filter 12 together with the inlet pressure

valve 14 prevents the inflow of body fluids into the

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reservoir chamber 10. Further, should the inlet
pressure valve 14 and the septum 6 both leak or other-
wise malfunction, the inlet ceramic filter 12 would per-
mit only a slow flow of body fluids to enter the
reservoir chamber 10, until body ambient pressure
is achieved, at which time some medication could diffuse through
the ceramic filter 12 but at a rate that would not be
hazardous to a typical patient in which the system would
be implanted.

The reservoir chamber 10 comprises a liquid-vapor por-
tion 16 which rests atop a reservoir of medication 18, the liquid
vapor portion 16 and the reservoir 18 being separated by
a flexible diaphragm 20. The liquid-vapor volume in the
vapor portion 16 preferably comprises a saturated vapor in
equilibrium with a small amount of Freon 113 liquid. Over
normal body temperatures, Freon 113 has a linear pressure
characteristic ranging from -4 psig (at 98°) to approx-
imately -2.5 psig (at 104°F). Using Freon 113, the medi-
cation reservoir 18 will be maintained at a pressure below
that of the human body pressure up to altitudes of 8500
feet. For patients who may live above that altitude,
other fluorcarbons at lower pressure may be employed. In
this way, should both the septum 6 and the inlet pressure
valve 14 leak, the effect would be to cause body fluids
to diffuse slowly, via the inlet ceramic filter 12, into
the medication reservoir 18 rather than to have a rapid
flow of medication enter into the body where it could
cause harm to the patient. Because of the pressure dif-
ferential between the body and the medication reservoir
18, medication will not flow from the reservoir 18 into
the body. As the amount of medication in the medication
reservoir 18 varies, the flexible diaphragm 20 moves up.
or down, with the Freon 113 being converted either from

liquid to vapor or vapor to liquid to provide an essentially constant pressure which will always be below one atmosphere and below normal body pressure. A reservoir chamber having a volume of approximately 10cc would be sufficient for most applications. This amount of concentrated medication, insulin for example, could be fatal if injected over a short time. The volume of the antechamber 8 is less than 10% the size of the reservoir chamber 10. In the worst case of leakage if medication leaked from the reservoir chamber 10 into the antechamber 8 and even if the antechamber 8 leaked as well, only diluted medication would enter the body gradually passing from an area of low pressure to one of higher pressure. There is thus little likelihood of the dose being fatal. As readily seen in Fig. 2, decreasing or expanding the size of the reservoir chamber 10 would be a simple modification because of the arrangement of elements in the system. Included in the reservoir chamber 10 is a dual pressure switch 22 which can comprise a reservoir fill switch 23 for indicating when the pressure in the reservoir chamber 10 reaches a predetermined level such as -2 psig and a second switch 25 for indicating when the pressure reaches -1 psig. Fill switch 23 is used during the filling procedure to indicate (by a telemetry system to be described later) when the level of medication in the reservoir chamber 10 has reached a specific value. Should body fluids leak into the medication reservoir 18 for any reason, an increase in pressure would result that would activate the second pressure switch 25. For example, when body fluids entering reservoir 18 reach a pressure of -1 psig, this would set off a subcutaneous electrical stimulation alarm system. By having the fill switch 23 set at a

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lower pressure than the body fluid leak detection pressure switch 25, the filling of the reservoir 18 can be accomplished without setting off an alarm signal.

In order to fill the reservoir chamber 10 with medication, a sequence of steps is followed. The antechamber 8 is normally filled with a saline or other innocuous solution which provides a buffer between the body and the reservoir chamber 10 and which if the septum failed would cause no harm to the patient. At the time of filling, a double hypodermic syringe 4 is directed into the antechamber 8 and saline is introduced into the antechamber 8 through one needle and exits through the other in order to flush the antechamber 8 with more saline. Once flushed, the antechamber 8 is checked for ~~pressure integrity with saline introduced under a~~ pressure integrity with saline introduced under a pressure which is less than that required to open the inlet pressure valve 14. When pressure integrity is determined, the antechamber 8 is flushed with the desired medication (such as insulin). Medication is then forced into the antechamber 8 at a pressure greater than that required to open inlet pressure valve 14. The insulin fills the medication reservoir 18 of the reservoir chamber 10 until the flexible membrane 20 contacts the dual pressure switch 22, forcing the reservoir fill switch 23, to generate a signal (e.g. at -2 psig) which indicates that the filling has been completed. The amount of medication required to fill the medication reservoir 18 is noted and then the antechamber 8 is flushed once again with innocuous saline solution. The entire reservoir chamber 10 is surrounded by a wall 24 and is isolated from the other elements of the system by means of the inlet pressure valve 14 and an interface pressure

valve 26 which connects the reservoir to a pulsatile

pump 28 which is shown in Fig. 4. The remaining elements

of the implanted portion 2 are also shown in Fig. 2: an

electronics section 30 with a battery subsection 32. As

is readily seen in Fig. 2, a hermetically sealed enclosure

34 surrounds the reservoir chamber 10 as well as the

pulsatile pump 28 (see Fig. 4), and the electronics section 30

with the battery subsection 32. To provide an enhanced safety

feature, a fluid detector 35 is provided between the

wall 24 and the hermetically sealed enclosure 34. Should

either the outer hermetic enclosure 34 leak or should

the reservoir chamber 10 leak, the fluid detector 35 is

placed at a location where the leaking body fluids or

medication would be detected. The fluid detector 35 could

be a very high resistance resistor (e.g. 10 megohms)

whose resistance drops significantly in the presence of

fluids. A malfunction signal to warn the patient if

such a leak is detected, is provided. Similarly a

medication leakage detector 37 in the liquid-vapor volume

16 would indicate when medication was leaking into that

chamber 16. This detector may also be a resistor whose

value will be significantly altered by the presence of

the medication. The medication leakage detector 37 when

actuated would set off a distinct subcutaneous electri-

cal stimulation alarm signal that can be detected by

the patient.

Fig. 4 illustrates the pulsatile pump 28 shown in

the top view of the implanted portion 2 shown in Fig. 3.

The interface pressure valve 26 shows where medication

enters the pulsatile pump 28 when the differential in

pressure between the reservoir chamber 10 and a medica-

tion storing means 200 (inside the pulsatile pump 28)

reaches a level sufficient to open the inlet pressure

pressure valve 26. In the preferred embodiment shown in

Fig. 4, this differential in pressure is caused by the

expansion of a spring bellows 202 in response to an

electrical pulse introduced to a pulsing coil 204 which

surrounds a plate 206 which is attached to the spring

bellows 202. When a pulse passes through the pulsing

coil 204, plate 206 is driven to a forward stop 208.

This action of expanding the storing means 200 causes the

interface pressure valve 26 to open, thereby allowing

medication from the reservoir chamber 10 to fill the

medication storing means 200. The plate 206 is a permanent

magnet (or, possibly, a magnetizable material) which moves

in response to a current induced magnetic force. When

current in the pulsing coil 204 ceases, the spring force

of the bellows 202 returns the plate 206 to a position

against a backstop member 210. The amount of travel of

plate 206 is thus fixed, rendering the stroke volume of

the pulsatile pump 28 constant and independent of the

electrical pulse current or pulse width into the pulsing

coil 204 as long as certain minimum currents and pulse

width is provided. The maximum pressure that can be

exerted by the pulsatile pump 28 is dependent on the

spring force that can be exerted by the bellows 202 as well

as the cross sectional area of plate 206 which is in

contact with the medication in the storing means 200.

More simply, $P_{max} = \dfrac{F}{A}$, where P_{max} is the maximum

pressure within the medication storing means 200, F is

the spring force of bellows 202, and A is the portion of surface area of plate 206 which is in contact with the medication in the medication storing means 200. Should a malfunction occur in the electronics and a continuous sequence of rapid pulses be introduced to the pulsing coil 204, causing the plate 206 to reciprocate, the return of the plate 206 to its original position against the backstop member 210 would be inhibited once the pressure in the storing means 200 exceeded p_{max}. The possibility of introducing drugs or other medication at an unsafe high pressure or high rate is thus essentially eliminated.

An outlet pressure valve 212 connects the storing means 200 in the pulsatile pump 208 with an outlet chamber 214. In operation, when the plate 206 returns toward its original position against backstop 210 after being reciprocated by the action of the pulsing coil 204 and the bellows 202, an increase in pressure in the storing means 200 results. When the pressure differential between the pressure in the storing means 200 and the pressure in outlet chamber 214 exceeds that required to open outlet pressure valve 212, medication flows into outlet chamber 214 from the medication storing means 200. To prevent large spurts or pulses of medication from entering the body over a short period of time, an elastic wall 216 and an output ceramic filter 218 are provided at the entrance to the outlet 220 of outlet chamber 214. The output ceramic filter 218 serves to resist the flow of medication from the outlet chamber 214 into the living body. The elastic wall 216 acts as a type of capacitance to flow, deforming when a pulse of medication is fed into the outlet chamber 214. The combination of the elastic wall 216 and the output ceramic filter 218 comprises a fluid or mechanical RC network that provides medication into the body within

an initial rise followed by a decaying flow. The time
constant which is fairly long, is determined by the
elasticity of the elastic wall 216 and the resistance
of the output ceramic filter 218. In addition, the out-
put ceramic filter 218 disallows medication from being
diffused into the body at a high rate, should both the
interface pressure valve 26 and the outlet pressure
valve 212 fail to seal.

Should valve 212 leak, there would be a slow dif-
fusion of ~~drug~~ medication through the ceramic filter 218 until the
pressure in the storing means 200 is essentially equal
to ambient body pressure. However, since the volume
means 200 is very small and since the ~~drug~~ medication fluid is
essentially incompressible, very little ~~drug~~ medication can diffuse
out and that amount only at a slow rate. Should both
valves 26 and 212 leak, body fluids would then diffuse
into the reservoir 18 because it is at a pressure below
body ambient pressure. ~~The drug~~ medication then could not diffuse
through the outlet ceramic filter 218 at an unsafe rate.

Safety of the output is best understood by consider-
ing the various pressure levels in the pulsatile pump 28.
With a bellows spring force which gives a maximum pressure,
P_{max}, of 15 psig and with an outlet pressure valve drop
of 5 psi, it is possible for the pulsatile pump 28 to pro-
vide a pressure as high as 10 psig in the outlet chamber
214. The pressure in the outlet chamber 214 is signifi-
cantly greater than the body ambient pressure of approxi-
mately 0 psig or the diastolic blood pressure which is
approximately 2 psig. The resistance of the output
ceramic filter 218 is selected to limit the drug flow to
a given safe level, for example less than 50% the maximum
pumping flow at which the pulsatile pump 28 is designed to
operate. As with the inlet ceramic filter 12 (of Fig. 2)

the outlet ceramic filter 218 also filters out

contaminants moving in either direction, from the

outlet chamber 214 into the body or from the body into

the outlet chamber 214. Also included in the pulsatile

pump 28 is a pressure transducer 222 which is shown ~~optimally~~

located in the outlet chamber 214. The pressure trans-

ducer 222 produces ~~pulses~~ an electrical output when a pressure

pulse of medication enters the outlet chamber 214. The

pressure transducer 222, in other words, detects the

pressure pulses which are provided each time the spring

bellows 202 returns the plate 206 to its original posi-

tion against backstop 210. By comparing the pulsing

from pulsing coil 204 with the pulsing generated by pres-

sure transducer 222, an indication is given as to whether

an absence or insufficient number of pulses or medication

have been provided to the body. An indication of extra

pulses of medication compared to the number of electrical

pulses may also be provided.

The pulsing signal to pulsing coil 204 as well as the

pulse output from the pressure transducer 222 are better

understood with reference to Fig. 5 a block diagram of

the electronics section 30 shown in Figs. 2 and 3. As

seen in Fig. 5, the electronics section 30 communicates

with a communication head 300 which is external to the

body, communicating through skin 5 by means of radio

signals. The communications head 300 provides both power

inputs and commands, including programmable inputs, to the

electronics section 30. Power is provided by means of

an alternating field, e.g. a magnetic field, which is

communicated to a pickup coil 304 which is implanted

together with the rest of the electronics section 30 in

the body. The pickup coil 304 receives an AC power

signal from communications head 300 and passes it on to a

full wave rectifier 306. One rectified output from the

full wave rectifier 306 enters a battery charge control

308 which provides a fixed DC charging signal to a power

cell 310. The power cell 310 can be a nickel-cadmium cell

which is readily rechargeable off a rectified signal at a

typical frequency of 20 kHz. Alternatively, a lithium-

type solid state battery can be used instead of the

nickel-cadmium cell in which case the charging circuitry

would be eliminated, the lithium type battery providing

sufficient power over a long term, thereby obviating the

need for recharging. The power cell 310 provides a biasing

voltage to a transistor switch 312, the output of which

enters the pulsing coil 204 previously described in the

context of the pulsatile pump 28. In addition to pro-

viding power to the power cell 310, rectified power is

also introduced to a DC to DC converter 314 the purpose

of which is to provide power at the proper levels to the

various loads in the system. In addition to the AC power

signal, pick-up coil 304 also receives a train of serial

digital bits from the communication head 300. The

digital bits comprise commands for programmable inputs

which are conveyed, via the pickup coil 304 to a command

receiver 316. The signals from the command receiver 316

enter a command decoder 318 which determines if the digital

bits are in a proper sequence and, if so, what action in

the system the commands dictate. It should be noted that

the full wave rectifier 306, the battery charge

controller 308, the command receiver 316, and the

command decoder 318 are powered only when an AC signal is

picked up by the pickup coil 304. This, of course,

prevents the possibility of detecting stray signals as

commands and provides power savings. To be sure, the

power savings achieved could make possible the use of the

aforementioned lithium cell which would not require re-

charging. From the command decoder 318, programmable

inputs and other commands can be provided to a number of

elements. A programmable base rate is entered into a base

rate memory unit 320 which stores a value indicating the

number of pulses of medication which are requested to be

provided to a patient during a normal preselected period

of time. A second programmable input is provided a

patient controlled rate memory unit 322 which stores a

value indicating a number of pulses of medication that

are requested to be introduced into the body over a given

period of time during which the patient eats a meal or

otherwise alters the chemical balance of the body (as by

exercising). Associated with the base rate memory unit

320 is a hardwired base rate limit control 324 which

sets a maximum rate that can override requests of the base

rate memory unit 320 which are excessive. Similarly, a

hardwired patient controlled rate limit control 326 pro-

vides a fixed maximum number of pulses which can be pro-

vided at a time after a meal or at other times and under

other conditions. As long as the base rate and patient

controlled rate values stored in memory units 320 and

322 respectively, do not exceed the hardwired values

fixed within limit controls 324 and 326, respectively,

an output pulse is provided to the input of transistor

switch 312 to stimulate a pulse output from pulsing

coil 204.   Should the rate of either memory unit 320 or

322 exceed the hardwired limits in the limit control

elements 324 or 326 respectively, a "rate request

exceeds limit" signal is fed from the limit control

element 324 or 326 into a programmable alarm generator

328 which provides an electrical signal to a stimulation

electrode 330 implanted subcutaneously.   By the stimulation

electrode 330, the patient is informed by means of a

subcutaneous stimulation that one of the memory units

320 or 322 is requesting more than the maximum allowable

number of pulses.

It should be noted that the signal to the stimulation

electrode 330 can serve the dual function of not only

providing the patient with a subcutaneous electrical

stimulation but may also be the source of a signal

detected by the communication head 300 communicated to

the patient or his physician either or both that a

failure has occurred.   As shown in Fig. 5, the electrode

330 will be isolated and should be insulated from the

outside of the hermetically sealed enclosure 34 of the

implanted portion 2.

A particularly significant feature of the invention

resides in the programmability of the alarm generator

328 based on input commands from the command decoder 318.

The alarm generator 328 can be switched on or off and

the voltage produced by the generator and hence the

electrode 330 can be varied in response to signals

emanating from the communication head 300 and channeled

through the command receiver 316 to the command decoder

318.   In addition, to check the proper operation of the

system, the command decoder 318 can receive test signals
which can simulate actual occurrences to determine whether
the circuitry in the electronic section 30 is operating
properly. For example, extra pulses from the command
decoder 318 can be entered into the hardwired limit
control elements 324 and 326. These extra pulses can be
added to the pulses provided by the base rate and the
patient controlled rate memory units. in order to exceed
the hardwired base rate and the hardwired patient-con-
trolled rate, respectively. When the rates are exceeded,
the alarm generator 328 will provide a signal. In this
way, the alarm generator 328 can be used to check the
operation of the limit control elements 324 and 326 and
also familiarize the patient with the corresponding
subcutaneous stimulation emitted by the tickle electrode
330. The programmable alarm generator 328 also receives
inputs from the pressure switch 22 and the fluid detector
35 both shown in Fig. 2. If body fluids leak into the
reservoir 18, the pressure switch 25 will be activated,
indicating this fault condition to the patient by means
of the activation of the alarm generator 328 and the
electrode 330. If the patient was unconscious, voltage
levels on the patient's skin at the site of the implanted
portion 2 could be used by the physician to indicate if a
malfunction has occurred and which malfunction it was.
Further, as previously described, should fluid leak out
of the reservoir chamber 10 and onto the lining of the
enclosure 34 or, alternatively, if body fluid should
leak in through the enclosure 34, the fluid detector 35
would sense such leakage and, as shown in Fig. 5,
would provide input to the alarm generator 328. Still
another input to the alarm generator 320 comes from

the power cell 310 associated with transistor switch 312.
The voltage level of the power cell 310 is communicated
to the alarm generator 328, a tickle or subcutaneous stimu-
lation being generated when the voltage is below a predeter-
mined level. Finally, referring back to the pulsatile
pump 28 of Fig. 4, the electrical pressure transducer 222
provides a signal which is compared to a programmed
"insufficient rate" value emanating from the command
decoder 318. If the number of pulses sensed by the
pressure transducer 222 over a specified period of time are
less than the number of pulses associated with the
"insufficient rate" command input, a pulse rate detector
332 will provide an output indicating that an insufficient
amount of medication is being provided to the patient over
the specified time. The output of pulse rate detector 332
(Fig. 5) also enters the tickle generator 328 to provide a
subcutaneous tickle detectable by the patient. It should
be noted that the various mentioned failures in the system
result in subcutaneous stimulations each of which may be
different in stimulation magnitude, duration, or
periodicity. For example, the stimulation may range
between one to four volts and may vary in frequency above
and below 20 pulses per second and most importantly, a
variety of pulse patterns may be used each unique to a
particular malfunction or warning. Additional warnings
that might be used are: (1) medication has leaked into the
liquid-vapor volume, (2) only 10% of the medication remains
in the reservoir, (3) only 5 days medication remains.

In addition to pulsing the pump coil 204, the outputs
of the limit control elements 324 and 326 also provide
input to a pulse recorder 334. Pulse recorder 334 maintains
a running history of how many electrical pulses have been

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provided to the pulsatile pump 28 since the last refill

of the reservoir 18 (in Fig. 1). An "interrogate" signal

from the command decoder 318 instructs the pulse recorder

334 to provide the history to a telemetry transmitter 336

which communicates the pulse history to a telemetry coil

338. The pulse recorder 334 would record both the number

of pulses delivered to the pumping coil 204 and the number

of pulses detected by the pressure transducer 222 and/or

the difference between these two numbers. The telemetry

coil 338, in turn, provides its output through radio

frequency signals to a telemetry receiving antenna in the

communication head 300. In addition to the pulse history

the telemetry transmitter 336 also receives, during

programming, inputs from the base rate memory unit 320

and patient controlled rate memory unit 322 which are transmitted

mit back to the communication head 300 that the desired

base rate and patient controlled rate, respectively, have

been programmed into the corresponding memory unit 320

or 322. Similarly, other key parameters 337 of the system

are also conveyed by means of the telemetry transmitter

336 back to the communication head 300. For example, the

exact pressure transducer output waveform would be tele-

metered. Of course, the pressure waveform signal would

only be transmitted when the telemetry system is powered.

Similarly, the reservoir fill switch 23 placed in the

reservoir chamber 10 to indicate when it has reached a

predetermined fill level is also connected via the

telemetry transmitter 336 and telemetry coil 338 to the

communication head 300 to indicate when the reservoir 18

has been filled with medication. Finally, a simulated

low battery voltage signal can be conveyed from the

command decoder 318 to the telemetry transmitter 336 to

check that portion of the status circuitry. As with the

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full wave rectifier 306, battery charge control 308, com-
mand receiver 316, and command decoder 318, the telemetry
transmitter 336 is powered only during programming *interrogation*
testing with simulation signals, and power cell charging.

Reference is now made to Fig. 6 which shows a method
of programming the patient controlled memory unit 322.
The significance of the method lies in the fact that it
provides two maximum running integral dose limits in
response to requests for medication. Two maximum
integral number of pulses for two different time periods
are provided. *Both are* ~~and they are both~~ independent of the time
of day and therefore would be effective regardless of
the patients eating or working schedule, which schedule *13*
change might be a result of the patient changing time
zones. In the sample graph of Fig. 6, a maximum of
eight pulses for a four hour period and twenty-four
pulses for any twenty-four hour period are imposed as
maximum running integral dose limits. These rate
settings can, of course, be altered depending on
patient needs and medication to be administered and time
periods other than 4 hours or 24 hours could be used.
In Fig. 6, the number of pulses is shown as a function
of time.

In Fig. 6, at midnight, the number of pulses that
are allowed in the 4 hour period is eight. Shortly after
8 A.M. five pulses are requested diminishing the number
of additional pulses allowed to three pulses. Prior to
noon, within the four hour time period, a five pulse
request is entered. In accordance with the maximum
running integral four hour restraint, only three pulses
are permitted but the remaining two pulses in the request
are stored in the memory unit 322 (Fig. 5) to be

executed at the end of the four hour period beginning

immediately after four hours past the delivery time for

the after breakfast pulsing. Shortly after noon, when

the four hours are over the two pulses are executed. It

should be noted that shortly after noon the three pulses

provided just before noon were subtracted from the eight

pulse allowance. The dispensing of three pulses prior

to noon is not eradicated until four hours thereafter, or

shortly before 4 P.M. Shortly before 4 P.M. the three

pulse allowance is automatically raised to six pulses,

accounting for the three pulses executed just before

noon. Shortly after 4 P.M., the allowance automatically

rises to eight pulses thereby accounting for the two

pulses executed shortly after noon. At approximately

6 P.M. the patient has dinner requiring five pulses and

the allowance diminishes to three pulses. Shortly be-

fore 10 P.M. the patient has a snack which requires two

pulses of medication diminishing the allowance to one

pulse. At approximately 10 P.M. the five pulses pro-

vided at dinner are no longer of import and the allow-

ance is raised by those five pulses to a six pulse

level allowance. The importance of Fig. 5 is readily

apparent when one considers the various time zones or

work schedules a patient may go through from time to

time in the course of his life. The program in Fig. 6

provides sufficient safety and flexibility for a wide

variety of patients.

Referring now to Fig. 7, the front view of a patient

programming unit 400 is shown. In the center of the

unit is a dial 402 which can be rotated to indicate the

size of a meal eaten by the patient or the amount of

exercise he has undergone, in order to provide inputs

indicating the amount of medication needed. Output

from the patient programming unit 400 ~~enters the telemetry input portion of the communication head 300 of Fig. 4~~ as commands. Whether or not the request is valid is determined in the electronic section 30 and is conveyed back to the ~~communication head 300~~ patient programming unit 400 by telemetry. A signal ~~to~~ the patient's programming unit 400 indicates whether his request has been satisfied. The patient programming unit 400 will be provided both with audio and visual outputs rendering it particularly useful for those patients having either visual or hearing handicaps.

In Fig. 8 is the rear view of the patient programming unit 400. The rear side of the patient programming unit 400 will provide information indicating the number of pulses sent at the last request (403); the time of the last request (404); and possibly (but ~~is~~ is not shown) the number of pulses which can be sent within the program restraints. By programming ROMS (not shown) in the patient's programming unit 400 in accordance with the running integral programs shown in Fig. 5 an "OK" or "TOO MUCH REQUESTED" video and/or audible output can be provided. The audio output would emanate from the loudspeaker 405. When the request leads to the dispensing of a pulse or pulses of medication, ~~a "PULSE SENT"~~ signal from the implanted portion 2 is relayed to the patient's programming unit 400.

It should be understood that alternative embodiments are contemplated by the present invention. For example, the antechamber 8 can comprise a vitreous carbon insert in the skull coupled with a tube directed to the reservoir chamber 10. The filling procedure and elements of the antechamber 8 (e.g. the septum ~~diaphragm~~ 6) would remain the same with the vitreous carbon insert. The inlet pressure valve 14 and filter 12 would still ~~also~~ separate the

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insert and tube from the reservoir chamber 10. Similarly,
in addition to the patient's programming unit 400, a
physician's unit may be provided which indicates: when
the medication reservoir 18 (of Fig. 1) has been filled,
the pulse history from the pulse recorder 334, and other
signals from the telemetry transmitter 336 of Fig. 4.
Such a physician's unit would be connected to the
telemetry portion of the communication head 300.